K033576

OMNI-FLOW® Medication Management System™

LifeShield® Latex-Free Primary IV Pump Set
Distal Microbore Patient Line, Convertible Pin, 72 Inch,
with 2 Pressure-Activated Anti-Siphon Valves, CLAVE® and
OPTION-LOK®

DEC - 4 2003

Special 510(K) Summary

1. Name of Submitter:

Abbott Laboratories
Hospital Products Division
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Establishment Registration # 1415939

2. Manufacturer and Establishment Registration Number:

Manufacturer	Sterilization Site
Abbott Hospitals, Limited Parque Industrial Itabo, S.A. Haina, San Cristobal Dominican Republic	Abbott Laboratories Hospital Products Division Hwy. 301 North Rocky Mount, NC 27801
Establishment Registration # 9613251	Establishment Registration # 1021343

3. Proprietary or Trade Name: LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch, with 2 Pressure-Activated Anti-Siphon Valves, Inline Cassette, Collection Bag, CLAVE® and OPTION-LOK® (LN 12566)

4. Common Name: Set, Administration Intravascular

5. Device Classification, Pancode and ProCode: Class II, 80, FPA

6. Performance Standards: Performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Set, Administration Intravascular. Set Administration Intravascular can be found in 21 CFR 880.5440.

7. Intended Use:
LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch, with 2 Pressure-Activated Anti-Siphon Valves, Inline Cassette, Collection Bag, CLAVE® and OPTION-LOK® is a single use device for the delivery of fluids from a container to a patient's vascular system.

The intended use and indications for use are the same as other commercially available IV administration sets designated for use with the Omni-Flow® Medication Management Systems™. This set is not intended for gravity use.

8. Indications for Use:
The device is used with the Omni-Flow® Medication Management System™ for intravenous infusion by or under the order of a licensed medical practitioner. The device can be used to simultaneously infuse up to four solutions/medications from both syringes and IV fluid containers.

9. Device Description:

The LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch, with 2 Pressure-Activated Anti-Siphon Valves, Inline Cassette, Collection Bag, CLAVE® and OPTION-LOK® is designed to be used exclusively with Omni-Flow® Medication Management Systems™. The set is equipped with two pressure-activated anti-siphon valves. The two valves limit gravity flow (free flow) to 1ml per hour when the set is primed and attached to a solution bag hanging vertically at full set extension (72 inches).

10. Statement of Substantial Equivalence:

The LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch, with 2 Pressure-Activated Anti-Siphon Valves, Inline Cassette, Collection Bag, CLAVE® and OPTION-LOK® is substantially equivalent to the LifeShield® Latex-Free Primary IV Pump Set with Distal Microbore Patient Line and Gravity Flow Prevention Valve, Convertible Pin, 110 Inch, with CLAVE® and OPTION-LOK® (LN 12162).

The modified primary set (LN 12566) is substantially equivalent to currently marketed primary set (LN 12162 in that :

Similarities:

1) Both are used for intravenous infusion. with the Omni-Flow® Medication Management System™.
2) Both can be used with the Omni-Flow® Medication Management System™ for intravenous infusion by or under the order of a licensed medical practitioner. Both devices can be used to simultaneously infuse up to four solutions/medications from both syringes and IV fluid containers.
3) Both are latex-free primary sets consisting of a Distal Microbore Patient Line, Convertible Pin, Inline Cassette, Collection Bag, (1) Integral Y-High Clave at the distal end of the patient line, and OPTION-LOK®.
4) Both sets have at least (1) Pressure Activated Anti-Siphon Valve (PAV) to provide free flow protection under specific head height conditions.
5) Both sets have components made from the same or similar material.
6) Both sets are not intended for use as a gravity set.

Differences:

1) The modified set contains two PAV"s located distal to the cassette. The current set has only (1) PAV located distal to the cassette.
2) The modified set has a total tubing length of 72 inches (nominal). The current set has a total tubing length of 110 inches (nominal).
3) The PAV's in the modified set contain a comparable silicone material cleared under K790062 (IV Administration Set with Backcheck), and are currently manufactured and sold by B. Braun Medical Inc. as a bulk /non-sterile item.

11. Predicate Device Information:

Information for IV Administration sets/set components previously cleared for commercial distribution and determined to be appropriate for use as predicates is provided below.

510(k) #	Product Name	Date Submitted	Clearance Date
K790062	IV Administration Set with Backcheck Valve (B. Braun Medical)	01/10/79	04/10/79
K832755	OmniFlow Infusion Pump & IV Sets	08/09/83	11/03/83
K882594	OmniFlow Therapist Infusion System & IV Sets	06/21/88	09/20/88
K915571	Clave Connector (ICU Medical)	12/12/91	09/21/92
K944125	Abbott LTE Infusion Pump & IV Sets	08/16/94	12/06/94
K971293	Lifeshield Primary IV Set with Backcheck Valve	04/04/97	06/27/97

12. Comparison to Legally Marketed Device(s)

Factors	**Subject Device (LN 12566)**	**Predicate Device(s) (LN 12162)**
Intended Use		
	Single use device for the delivery of fluids from a container to a patient's vascular system.	Same
Indications for Use		
	The device is used with the Omni-Flow® Medication Management System™ for intravenous infusion by or under the order of a licensed medical practitioner. The device can be used to simultaneously infuse up to four solutions/medications from both syringes and IV fluid containers.	Same
Technology		
➢ Basic Operating Principle	Adminstration/infusion of intravenous medications to a patient's vascular system with the assistance of an infusion pump.	Same
➢ Gravity Flow Protection	Provide gravity flow (free flow) protection at full vertical extension of the set (72 inches).	Provide gravity flow (free flow) protection up to a 36 inch head height.

LifeShield® Latex-Free Primary IV Pump Set
Distal Microbore Patient Line, Convertible Pin, 72 Inch,
with 2 Pressure-Activated Anti-Siphon Valves, CLAVE® and
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Factors	Subject Device (LN 12566)	Predicate Device(s) (LN 12162)
Technology (continued)		
➢ IV Line Type	Primary Patient Line	Same
➢ Infusion Pump Compatibility	Omni-Flow® Medication Management Systems™	Same
➢ Infusion Fluid Types	General Hospital	Same
Design/Components		
➢ Pressure Activated Anti-Siphon Valves (PAV)	(2) PAV's	(1) PAV
➢ Semi-Rigid Adapters (bonds PAV to set)	(4) Semi-Rigid Adapters	(1) Semi-Rigid Adapter
➢ Access Sites	(1) Integral Y-High Clave (distal)	Same
➢ Total Tubing Length	72 inches (Nominal)	110 inches (Nominal)
➢ Tubing Type	Distal Microbore	Same
➢ Convertible Piercing Pin	Yes	Same
➢ CAIR Clamp	Yes	Same
➢ Drip Chamber	Yes	Same
➢ In-Line Integral Cassette	(1) Patient Line Port, (1) Collection Bag Port, (4) Secondary Line Ports	Same
➢ Roller Clamp	Yes	Same
➢ OPTION-LOK® Male Adapter	Yes	Same
➢ Slide Clamp	Yes	Same
➢ Collection Bag	Yes	Same
Materials		
➢ Pressure Activated Anti-Siphon Valves (PAV) Housing	Polycarbonate	Same
➢ Pressure Activated Anti-Siphon Valves (PAV), Disc	Silicone	Same
➢ All Other Components	Same	Same
Manufacturing Processes and Sterilization		
All Components	Same	Same
Packaging		
➢ Assembled Set	Paperboard Carton	Same
➢ Shipping Container	Corrugated Fiberboard	Same

13. Summary of Safety and Effectiveness

The LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch, with 2 Pressure-Activated Anti-Siphon Valves, CLAVE® and OPTION-LOK® (LN 12566) as described in this submission is substantially equivalent to the predicate Lifeshield Primary Set (LN 12162), in that both sets have:

1) the same intended use,
2) the same indication for use,
3) the same fundamental technology and operating principle,
4) the same or similar materials of construction for all components,
5) the same manufacturing and sterilization processes, and
6) the same packaging.

14. Statement of Safety and Effectiveness

The LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch,with 2 Pressure-Activated Anti-Siphon Valves, CLAVE® and OPTION-LOK® (LN 12566) meets the functional claims and intended use as described in the product labeling, and is substantially equivalent to, and as safe and effective as, the LifeShield® Latex-Free Primary Pump Set with Distal Microbore Patient Line, Convertible Pin, 110 Inch, with Pressure-Activated Anti-Siphon Valve, Inline Cassette, Collection Bag, CLAVE® and OPTION-LOK® (LN 12162).

Prepared and submitted November 12, 2003 by:

Patricia Melerski
Manager Regulatory Affairs Device Registration
Abbott Laboratories
Hospital Products Division D389, J45-2N
200 Abbott Park Road, IL 60064-6133
Phone: 847/938-3718
Fax: 847/938-7867

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Abbott laboratories
Ms. Patricia Melerski
Manager, Regulatory Affairs Device Registration
Hospital Products Division
D-389, Bldg. J45-2N
200 Abbott Park Road
Abbott, Park, Illinois 60064-6133

Re: K033576
Trade/Device Name: LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch, with 2 Pressure-Activated Anti-Siphon Valves, Inline Cassette, Collection Bag, CLAVE® and OPTION- LOK® (LN 12566)
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 12, 2003
Received: November 13, 2003

Dear. Ms. Melerski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

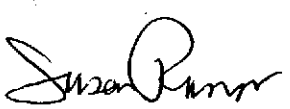
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

LifeShield® Latex-Free Primary IV Pump Set
Distal Microbore Patient Line, Convertible Pin, 72 Inch,
with 2 Pressure-Activated Anti-Siphon Valves, CLAVE® and
OPTION-LOK®

Indications for Use Statement

510(k) Number (if known)

Device Name: LifeShield® Latex-Free Primary IV Pump Set Distal Microbore Patient Line, Convertible Pin, 72 Inch, with 2 Pressure-Activated Anti-Siphon Valves, Inline Cassette, Collection Bag, CLAVE® and OPTION-LOK® (LN 12566)

Indications For Use: LifeShield® Latex-Free Primary IV Pump Set (LN12566) has the following indications for use:

The device is used with the Omni-Flow® Medication Management System™ for intravenous infusion by or under the order of a licensed medical practitioner. The device can be used to simultaneously infuse up to four solutions/medications from both syringes and IV fluid containers.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) **OR** **Over-The_Counter Use**____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033576